

APR 27 2001

**Fresenius Priming Set with Needleless Access Port
510(k) Premarket Notification****Summary of Safety and Effectiveness**

E. Substantial Equivalence:**1. Is the product a device?**

YES - The Fresenius Priming Set with Needleless Access Port is a device pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES - The intended use for the Fresenius Priming Set with Needleless Access Port™ is equivalent to that for the Medisystems Dialysis Priming Set with Needleless Access Port.

Fresenius Priming Set with Needleless Access Port™**Intended Use**

The Fresenius Priming Set with Needleless Access Port is intended to be used during hemodialysis:

- 1. For priming the blood circuit prior to commencing hemodialysis;*
- 2. For use in the administration of intravenous fluids from a vented bottle or collapsible container.*
- 3. For needleless administration or sampling of fluid prior to or during hemodialysis.*

**Medisystems Dialysis Priming Set with Needleless Access Port
(#K971860, 8/18/97)****Intended Use**

The proposed Dialysis Priming Sets are indicated for use to provide a means to deliver fluids and medicaments from a collapsible container or vented bottle into a patient's vascular system during dialysis procedures.

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO - The technological characteristics of the Fresenius Priming Set with Needleless Access Port are equivalent to those of the Medisystems Dialysis Priming Set with Needleless Access Port.

Like the Medisystems Priming Set, the Fresenius Priming Set consists of:

- a flexible drip chamber with a spike for attachment to the solution container;

**Fresenius Priming Set with Needleless Access Port
510(k) Premarket Notification**

Summary of Safety and Effectiveness

- an adjustable clamp that regulates flow (items #4 and #5), at approximately 20 drops per ml;
- a flexible delivery tube;
- a two-port connector with one female connector and one male connector— The female luer connector allows the connection of devices with a male luer, such as a syringe. A line clamp is used to occlude fluid flow from the female luer. The male connector allows the priming set to be attached to hemodialysis blood tubing sets with female luer connectors;
- a line clamp on the female luer line.

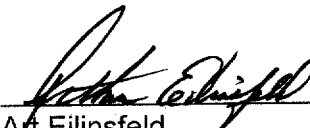
In addition, the packaging system and sterilization cycle of the Fresenius Priming Set with Needleless Access Port are identical to those used for other commercially available Fresenius products.

4. Does descriptive or performance information demonstrate equivalence?

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Fresenius Priming Set with Needleless Access Port, and demonstrates that it is substantially equivalent to the Medisystems Dialysis Priming Set with Needleless Access Port cleared under #K971860 (8/18/97).

F. Safety Summary

The Fresenius Priming Set will be thoroughly tested and required to meet all final release specifications prior to distribution. The results of this testing, which includes, but is not limited to: sterility, pyrogenicity, physical testing and visual examination of both in-process and finished product, indicate that the device is safe and effective for its intended use. In addition, Instructions for Use are provided, which contain instructions for proper use of the device as well as warnings and cautions.


Art Eilinsfeld
Director of Regulatory Affairs

1/26/01
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 27 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Nicole Riek
Regulatory Affairs Specialist
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K010268
Fresenius Priming Set with Needleless Access Port™
Model 04-9002-9
Dated: January 25, 2001
Received: January 29, 2001
Regulatory Class: II
21 CFR §876.5820/Procode: 78 KOC

Dear Ms. Riek:

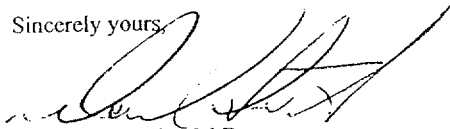
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041, or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)



Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius Priming Set with Needleless Access Port

Indications for Use:

The Fresenius Priming Set with Needleless Access Port is intended to be used during hemodialysis:

1. For priming the blood circuit prior to commencing hemodialysis;
2. For use in the administration of intravenous fluids from a vented bottle or collapsible container.
3. For needleless administration or sampling of fluid prior to or during hemodialysis.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

Fresenius Medical Care North America

[Signature]
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

K010268